AD-A212 635

DTIC FILE COPY

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

1. REPORT NUMBER	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) A Quality Assurance Model of Operation Mortality in Coronary Artery Surgery		5. TYPE OF REPORT & PERIOD COVERED
		6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) Edwards FH, Albus RA, Zajtchuk R, Graeber GM, and Barry M.		8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS Division of Surgery Walter Reed Army Institute of Research Washin-ton, D.C. 20307-5100		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS US Army Research and Development Command Fort Detrick, Frederick, MD 27101		12. REPORT DATE
		13. NUMBER OF PAGES 4
14. MONITORING AGENCY NAME & ADDRESS (If different from Controlling Office) Walter Reed Army Institute of Research Washington, DC 20307-5100		15. SECURITY CLASS. (of this report)
		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

Approved for public release, distribution unlimited

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

DTIC ELECTE SEP 20 1989 S D D

18. SUPPLEMENTARY NOTES

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

BEST AVAILABLE COPY

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Quality assurance coronary artery bypass grafting (CABG) surgery requires comparison of operative mortality against an accepted standard of care. Raw mortality statistics are unacceptable in this context, and risk factor analysis [illegible]ential. However, this principle has not been adequately demonstrated in [illegible] reports. [illegible] in this [illegible] was to develop a [illegible] model of [illegible] CABG mortality and illustrate its [illegible] coronary artery [illegible] derived [illegible]

DD FORM 1473 EDITION OF 1 NOV 65 IS OBSOLETE

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

A Quality Assurance Model of Operative Mortality in Coronary Artery Surgery

Fred H. Edwards, MD, Robert A. Albus, MD, Rostik Zajtchuk, MD, Geoffrey M. Graeber, MD, and Michael Barry, MD

Department of Cardiothoracic Surgery, Walter Reed Army Medical Center, Washington, DC; Walter Reed Institute of Research, Washington, DC; and F. Edward Hebert School of Medicine, Uniformed Services University of Health Sciences, Bethesda, Maryland

Quality assurance in coronary artery bypass grafting (CABG) surgery requires a comparison of operative mortality against an accepted standard of care. Raw mortality statistics are unacceptable in this context, and risk factor analysis is essential. However, this principle has not been adequately demonstrated in previous reports. Our goal in this study was to develop a risk model of accepted CABG mortality and illustrate its proper use in coronary artery surgery. The model was derived from a Bayesian analysis of 6,630 patients undergoing CABG in the Coronary Artery Surgery Study (CASS) registry. Age, sex, ventricular function, previous myocardial infarction, extent of coronary artery disease, unstable angina, and surgical priority were used by the model to sort patients into risk categories. From January 1984 through December 1987, 840 patients underwent isolated CABG at our hospital. With raw mortality data, the 3.9% (33/840) mortality of our patients was significantly different from the 2.3% (153/6,630) CASS mortality ($p < 0.001$). When our patients were entered into the CASS model for risk stratification, however, our CABG mortality conformed to the CASS experience. These results illustrate the fallacy of using raw mortality statistics for interinstitutional comparisons. This type of risk model is a fundamental element of CABG quality assurance.

(Ann Thorac Surg 1989;47:646–9)

An effective quality assurance program compares operative results against accepted standards of care. However, it is quite difficult to apply this principle to the field of coronary artery surgery [1–4]. The major obstacle has been the need to account for all important risk factors so that patients can be sorted into appropriate risk categories [1, 3–5]. Certainly the use of raw statistical data without allowing for risk stratification is a disservice to patient and physician alike [4–6]. It should be possible to use a model of accepted operative mortality to compare the predicted results of the model against the observed results of patients in similar risk categories.

We have investigated this approach by developing a Bayesian model of the Coronary Artery Surgery Study (CASS) experience for comparison against our own operative experience. The model has been derived with particular attention to ensure that patients are closely matched and stratified according to preoperative risk factors.

Risk stratification is an essential element of quality assurance [1, 2, 4–7]. The CASS group developed a logistic risk equation [8] to address this issue, but its cumbersome nature has precluded practical application [1]. More recently, we [4] have used a Bayesian algorithm to sort patients into major risk categories. Our success in using this method to model our own operative experience encouraged us to use a similar system to represent the CASS results. The technique is completely general and can be applied to other clinical areas.

Material and Methods

The Bayesian model was developed according to previously published guidelines [4, 9], and was designed to predict the probability of death after coronary artery bypass grafting (CABG) based on the reported experience of the CASS registry. There are several studies detailing the composition of CASS registry patients, but the most complete for the purpose of this study was that of Kennedy and colleagues [10] from the Coordinating Center for Collaborative Studies in Coronary Artery Surgery.

Two prognostic categories were considered: survival and death. Seven preoperative patient variables generally regarded as important risk factors were selected: age, sex, ejection fraction, extent of coronary artery disease, previous myocardial infarction, unstable angina, and surgical priority. These risk factors were used to determine the conditional probabilities associated with each prognostic category (Table 1). The resultant conditional probability matrix was then incorporated into a computerized Bayesian algorithm to serve as a model of CASS operative mortality. For any given patient, the model analyzes these seven risk factors to generate a prediction of the probability of operative death for that patient based on the reported CASS experience.

The patient population for entry into this model was drawn from the recent operative experience at Walter

Presented at the Thirty-fifth Annual Meeting of the Southern Thoracic Surgical Association, Marco Island, FL, Nov 10–12, 1988.

Address reprint requests to Dr Edwards, Department of Thoracic Surgery, Walter Reed Army Medical Center, Washington, DC 20307-5001.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

Table 1. Conditional Probabilities From CASS Registry[a,b]

Variable	Survivors (n = 6,477)	Deaths (n = 153)
Age (yr)		
<50	1,738 (27)	22 (14)
50–70	4,530 (70)	113 (74)
>70	209 (3)	18 (12)
Sex		
Male	5,464 (84)	105 (69)
Female	1,013 (16)	48 (31)
Ejection fraction (%)		
>50	3,839 (78)	74 (70)
30–50	977 (20)	27 (25)
<30	102 (2)	5 (5)
Coronary artery involvement		
Left main	976 (15)	37 (24)
3 Vessels	3,198 (50)	92 (61)
2 Vessels	2,018 (31)	43 (28)
1 Vessel	1,196 (19)	17 (11)
Previous myocardial infarction	3,413 (53)	84 (55)
Unstable angina	2,652 (41)	96 (63)
Surgical priority		
Routine	5,129 (80)	89 (59)
Urgent	1,062 (17)	39 (26)
Emergent	189 (3)	23 (15)

[a] The number of patients in each prognostic category (survivors or deaths) that have the designated risk factor. The percentage of patients is shown in parentheses. For example, of those who survived, 1,738 or 27% (1,738/6,477) were less than 50 years old. [b] Ejection fraction calculations were based on a total of 5,024 patients, coronary artery involvement was based on 6,564 patients, and surgical priority was based on 6,531 patients as reported by Kennedy and colleagues [10]. The other calculations were based on 6,630 patients.

Table 2. Characteristics of the 840 Patients[a]

Variable	Survivors (n = 807)	Deaths (n = 33)
Age (yr)		
<50	180 (22)	3 (9)
50–70	551 (68)	23 (70)
>70	76 (9)	7 (21)
Sex		
Male	693 (86)	24 (73)
Female	114 (14)	9 (27)
Ejection fraction (%)		
<30	34 (4)	4 (12)
30–50	168 (21)	12 (36)
>50	605 (75)	17 (52)
Coronary artery involvement		
Left main	127 (16)	8 (24)
3 Vessels	549 (68)	26 (79)
2 Vessels	186 (23)	7 (21)
1 Vessel	72 (9)	0
Previous myocardial infarction	353 (44)	15 (45)
Unstable angina	109 (14)	13 (39)
Surgical priority		
Elective	517 (64)	14 (42)
Urgent	201 (25)	10 (30)
Emergency	89 (11)	9 (27)

[a] Numbers in parentheses are percentages.

Reed Army Medical Center. From January 1984 to January 1988, 895 consecutive patients underwent isolated CABG at our hospital. Insufficient clinical information eliminated 38 of them (none of whom died) from the study. Seventeen patients were taken to the operating room with an evolving myocardial infarction and severe hemodynamic compromise, thereby making them inappropriate for comparison with CASS patients. The remaining 840 patients made up the population evaluated by the CASS model (Table 2).

Surgical priority was assigned using definitions similar to those used by the CASS group [4, 8, 10]. Emergency operations were usually performed within one hour of catheterization or clinical deterioration. Procedures were classified as urgent if CABG was necessary within two days of catheterization. All others were considered elective.

Operations were performed using cardiopulmonary bypass and moderate systemic hypothermia with topical cooling. Cold potassium crystalloid or blood cardioplegia was used in all patients. Venting was usually established by way of the ascending aorta, but this depended on the preference of the operating surgeon. Distal coronary anastomoses were performed first, and the proximal anastomoses were performed over a partial occlusion clamp during the rewarming phase.

The presence or absence of the seven risk factors was noted for each of the 840 patients. Individual patient data were then entered into the CASS model, and a prediction of the probability of operative death was obtained for each patient. This allowed the patients to be grouped into risk categories, as shown in Table 3. The observed mortality for each category was obtained by tabulating the actual number of deaths that occurred in that group. A compar-

Table 3. Predicted Versus Observed Operative Mortality

Predicted Mortality (%)	Observed Mortality[a] (%)	95% Confidence Limits[b]
<5	2.7 (17/625)	1.6%–4.4%
5–25	3.5 (5/139)	1.3%–8.6%
25–50	13.7 (7/51)	6.1%–26.8%
>50	16.0 (4/25)	5.2%–36.9%
>75	40.0 (2/5)	7.3%–82.9%

[a] Within the parentheses, the numerator is the number of deaths and the denominator is the total number of patients in that risk category. [b] The confidence limits indicate that one can be 95% certain that the "true" observed mortality will lie within the specified interval.

ison of the predicted and observed mortality is also shown in Table 3.

Results

In our population, 33 deaths occurred at some point during the hospitalization for CABG. The overall mortality for the group of 840 patients was 3.9% (33/840). Urgent or emergent operations made up 37% (309/840) of this series and accounted for 58% (19/33) of the deaths. Forty-three of the 840 patients were undergoing reoperative CABG. Additional clinical details of the patient population are given in Table 2.

Using only raw mortality data, a χ^2 analysis showed that the CASS mortality of 2.3% (153/6,630) is significantly less than the 3.9% mortality of our series ($p < 0.001$). When our patients are stratified according to risk, however, the operative mortality in our series is actually less than what would be anticipated from the CASS experience. As an example, 25 patients were predicted to have an operative mortality of more than 50% (see Table 3). Based on the CASS experience, at least 13 of these patients would have been expected to die after CABG. In fact, only 4 of them—or 16%—died, indicating that our results were in keeping with the standards of the CASS group. The same can be said for each of the remaining risk categories.

Comment

These results illustrate the fallacy of using raw mortality data to analyze operative results. A valid comparison must account for risk factors that permit stratification into patient subgroups that are at different levels of risk for CABG procedures [2, 3, 5, 7, 8]. Once patients have been sorted into such risk categories, then reasonable interinstitutional comparisons can be made.

It is clearly desirable to use a model that analyzes individual patient risk factors to generate an estimate of the probability of operative death for the given patient. The model should be able to account for a large number of risk factors and should be sufficiently flexible to undergo changes in its data base as changes in the patient population occur with time. Both logistic risk equations [8] and the theorem of Bayes [4] satisfy these requirements. Logistic equations, however, have been somewhat difficult to apply on a practical basis [1, 4]. We believe that Bayesian algorithms offer more flexibility in this clinical context, and have chosen to develop our model using previously described Bayesian techniques [4, 9]. Certainly logistic regression models would be acceptable as well.

Regardless of the mathematical algorithm, one must select appropriate risk factors for consideration. There is an enormous body of information suggesting the most important risk factors for CABG, but conclusions vary from one report to another [1–4, 7, 8, 10–14]. We have chosen those patient parameters that are generally regarded as significant predictors of operative mortality [5, 7, 10, 12, 13]. As we [4, 9] have stated in earlier studies, we believe that a problem of this complexity requires the analysis of a large number of parameters. Certainly reoperation should ideally be included among the list of important risk factors. However, it is not possible to obtain all the information we would like from published CASS reports.

In deciding to use CASS for our data base, we were confronted with the choice of using all available data from one report or perhaps gathering more data from reports published at different times. However, because it is necessary to base the Bayesian conditional probabilities on a single patient population, we relied on a single report [10]. The use of information gathered from reports that span several years may introduce temporal variables that would adversely affect the validity of the model.

Our choice of CASS to represent a standard of care was completely arbitrary. There are a number of reasonable objections to this choice. Generally the CASS population is made up of patients falling into the lower end of the CABG risk spectrum [3, 12, 14]. In addition, many of these CASS patients underwent CABG a decade ago and therefore may not represent a true reflection of current risks. We recognize that other objections to the CASS registry can be raised [11–13], but we believe that CASS is a reasonable choice in this clinical context. We would not contend that CASS results are the best possible, but they do reflect at least an acceptable average standard of care [8, 11]. As mentioned, the approach we have used is completely general, and others may choose an alternative to represent the standard.

The major shortcoming of this study is that the CASS model has not been tested against CASS registry patients to confirm its validity. Statistical theory dictates that the Bayesian model will provide an accurate portrayal of the CASS experience, but without direct access to that registry, that cannot be verified. Perhaps such information from this government-funded study can be made available in the future so that the development of operative risk models can be facilitated.

It should be emphasized that no attempt has been made here to identify the most important risk factors. That is the task of variate analysis, which has been described in great detail in numerous other publications. The purpose of the Bayesian algorithm is to use preoperative patient risk factors to generate a prediction of the probability of operative death for a single given patient. Although it may be important to recognize the most important risk factors derived from large patient surveys, that information has little relevance to the single patient who is seen with a myriad of clinical characteristics that are not specifically addressed in these large trials. One must be able to predict the risk to that individual patient.

The algorithm presented here allows the surgeon to do exactly that. One enters the preoperative risk factors of the patient into the computer program, and the program uses a Bayesian formula to estimate the probability of operative death based on the data base of previous clinical experience.

In recent years, CABG operative mortality has come under close investigation. As responsible surgeons we welcome that scrutiny, but we must insist that standards of comparison fully account for the preoperative risk factors associated with CABG. The use in 1986 of raw

mortality statistics by the Department of Health and Human Services Health Care Financing Administration illustrates the misconceptions that can arise from inappropriate application of unsorted patient data [5, 15]. The Society of Thoracic Surgeons [5] has responded with a statement of concern expressing serious reservations about the use of Health Care Financing Administration data to suggest a "quality of care" standard. If we condemn this simplistic application of mortality data, though, we are obligated to propose a more acceptable alternative. The statement of concern emphasizes that risk factors predictive of operative mortality must be identified and subjected to appropriate statistical analysis before comparisons of mortality rates between institutions can be made. It further encourages the development of statistical models to sort patients into risk categories.

In this study, we have presented such a model of operative risk. Although this model may not be ideal, it does provide an improved instrument of quality assurance that is based on sound principles of surgical risk assessment. Techniques of this kind may encourage other institutions to critically review their operative results by making valid comparisons against a selected standard.

References

1. Pierpont GL, Kruse M, Ewald S, et al. Practical problems in assessing risk for coronary artery bypass grafting. J Thorac Cardiovasc Surg 1985;89:673.
2. Takaro T, Ankeney JL, Laning RC, Peduzzi PN. Quality control for cardiac surgery in the Veterans Administration. Ann Thorac Surg 1986;42:37–44.
3. Hlatky MA, Califf RM, Harrell FE, et al. Comparison of predictions based on observational data with the results of randomized controlled clinical trials of coronary artery bypass surgery. J Am Coll Cardiol 1988;11:237.
4. Edwards FH, Albus RA, Zajtchuk R, et al. Use of a Bayesian statistical model for risk assessment in coronary artery surgery. Ann Thorac Surg 1988;45:437–40.
5. Kouchoukos NT, Ebert PA, Grover FL, Lindesmith GG. Report of the Ad Hoc Committee on Risk Factors for coronary artery bypass surgery. Ann Thorac Surg 1988;45:348–9.
6. Hatcher CR Jr. There is life outside the operating room. Ann Thorac Surg 1988;45:117–21.
7. Naunheim KS, Fiore AC, Wadley JJ, et al. The changing profile of the patient undergoing coronary artery bypass surgery. J Am Coll Cardiol 1988;11:494.
8. Kennedy JW, Kaiser GC, Fisher LD, et al. Multivariate discriminant analysis of the clinical and angiographic predictors of operative mortality from CASS. J Thorac Cardiovasc Surg 1980;80:876.
9. Edwards FH, Graeber GM. The theorem of Bayes as a clinical research tool. Surg Gynecol Obstet 1987;165:127–9.
10. Kennedy JW, Kaiser GC, Fisher LD, et al. Clinical and angiographic predictors of operative mortality from the Collaborative Study in Coronary Artery Surgery (CASS). Circulation 1981;63:793.
11. Pluth JR. Operative mortality and morbidity for initial and repeat coronary artery bypass grafting [Editorial]. Ann Thorac Surg 1984;38:552–3.
12. Anderson RP. Will the real CASS stand up? A review and perspective on the Coronary Artery Surgery Study. J Thorac Cardiovasc Surg 1986;91:698.
13. Junod FL, Harlan BJ, Payne J, et al. Preoperative risk assessment in cardiac surgery: comparison of predicted and observed results. Ann Thorac Surg 1987;43:59–64.
14. Weinstein GS, Levin B. The Coronary Artery Surgery Study. A critical appraisal. J Thorac Cardiovasc Surg 1985;90:541.
15. Hanlon CR. The assurance of quality. Am Coll Surg Bull 1987;72(Dec):5.